GOVERNMENT OF INDIA
AYURVEDA,YOGA & NATUROPATHY,UNANI,SIDDHA AND HOMEOPATHY (AYUSH)
LOK SABHA

UNSTARRED QUESTION NO:1028
ANSWERED ON:21.07.2017
Research Activities in Ayurveda
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Will the Minister of AYURVEDA,YOGA & NATUROPATHY,UNANI,SIDDHA AND HOMEOPATHY (AYUSH) be pleased to state:

Will the Minister of AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH) be pleased to state:

(a) the details of the study and research activities in Ayurveda including literary and conceptual study, clinical and therapeutic research and drug development research during the last three years and the current year;

(b) whether toxicity has been reported in Ayurvedic products which lead to health problems among the users and if so, the details thereof along with preventive measures taken by the Government in this regard;

(c) whether storage conditions can also alter the bioavailability of herbal medicines, which may lead to loss of activity, fungal or bacterial contamination resulting into batch to batch variation; and

(d) if so, the measure taken to deliver consistent marketed formulation and check quality of ayurvedic products?

Answer

ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA,
YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY
(SHRI SHRIPAD YESSO NAIK)
(a): Ministry of AYUSH has set-up Central Council for Research in Ayurvedic Sciences (CCRAS) as apex body for formulation and development of Ayurvedic medicines for various diseases.

Year wise details of the study and research activities in Ayurveda including literary and conceptual study, clinical and therapeutic research and drug development research undertaken by CCRAS during the last three years and the current year are as under :-

2014-2015
i. Eight Clinical Research completed.
ii. A total 18 drugs were studied pharmacognostically.
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iii. Under Drug Standardization, 25 singles drugs have been carried out.
iv. Toxicological study of three coded drugs completed. Biological activity of one drug completed.
v. Eight books have been published.
vi. Five Intra Mural Literary Research projects completed.

2015-2016
i. 10 Clinical Research completed.
ii. Three Intra Mural Medicinal Plant Research projects completed.
iii. Under Drug Standardization, 54 singles drugs and 28 compound formulations have been carried out.
iv. Five Intra Mural Pharmacological Research Projects completed.
v. Eight books published. Besides this, three Intra Mural Literary Research projects completed.

2016-2017
i. Ten Clinical Research completed.
ii. Five Intra Mural Medicinal Plant Research projects completed.
iii. Under Drug Standardization, 88 singles drugs and 33 compound formulations have been carried out.
iv. Three Intra Mural Drug Standardization Research projects completed.
v. One Intra Mural Pharmacological Research Project completed.
vi. Nine books have been published. Besides this, three Intra Mural Literary Research projects completed.

2017-2018 (upto June)
i. 20 Clinical Research completed.
ii. Under Clinical Research, One Intra Mural Research project completed.
iii. Under Drug Standardization Programme, five IMR projects competed. Under Medicinal Plant Research, one project completed.

(b): CCRAS has informed that toxicity has not been reported in the clinical trials conducted by them.
Rule 158-B of the Drugs & Cosmetics Rules, 1945 seeks proof of safety and effectiveness for the purpose of licensing of various categories of Ayurvedic, Siddha and Unani drugs. Enforcement of these provisions is under the purview of the State Licensing Authorities appointed by the State Governments.
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Such Ayurvedic, Siddha and Unani drugs containing any of the potentially hazardous ingredients of plant, animal or mineral origin as specified in the Schedule E(1), Rule 161(2) of the Drugs and Cosmetics Rules, 1945, are required to be taken under medical supervision. In this regard an Advisory has been issued on 1st February, 2016 for Manufacturers of Ayurvedic, Siddha and Unani drugs for ensuring to imprint 'Caution: to be taken under medical supervision' both in English and Hindi on the labels of all such Ayurvedic, Siddha and Unani drugs which contain potentially hazardous ingredients of plant, animal or mineral origin as specified in the Schedule E(1) of the Drugs and Cosmetics Rules, 1945.
There is a specific category of herbo mineral or metallic Ayurvedic medicines called Rasaushadies or Rasa yoga. Many of such medicines make use of heavy metals like Mercury, Arsenic and Lead as ingredients after subjecting them to a series of processes called Shodana, Marana, Amritkaram etc. to render them safe and therapeutically effective. Separate GMP of Rasaaushadhies have been made mandatory under the provision of Drugs & Cosmetics Rules.
(c) & (d): Herbal Medicines are not covered in the provisions of Drugs and Cosmetics Act, 1940 and Rules there under, and hence are not recognized as a class of medicines in India. However, It is a scientific fact that the quality, efficacy, potency, shelf life and batch to batch consistency of plant material based products are affected by storage conditions.
Pharmacopoeial Standards of ayurvedic drugs are prescribed in the Ayurvedic Pharmacopoea along with permissible limit of heavy metals, aflatoxins, pesticide residue and microbial load. For manufacturing of ayurvedic products of assured quality in accordance with these standards
Shelf life of various categories of ayurvedic drugs is also notified under Drugs and Cosmetics Rule, 1945 and it is mandatory for the manufacturer to comply with Good Manufacturing Practices for obtaining manufacturing license.
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